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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,839	11/25/2003	Wendy Maury	IOWA:035USD1	3197

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EXAMINER

LUCAS, ZACHARIAH

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 10/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/721,839

Applicant(s)

MAURY ET AL.

Examiner

Zachariah Lucas

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,9-15,18-38 and 40 is/are pending in the application.
- 4a) Of the above claim(s) 10-15,25,26 and 29-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,9,18-24,27,28,34-38 and 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1, 9-15, 18-38, and 40 are pending in the application.
2. In the prior action, mailed on April 7, 2005, claims 1, 8-15, and 18-40 were pending in the application. In the action, claims 1, 8, 9, 18-24, 27, 28, and 34-40 were rejected; and claims 10-15, 25, 26, and 29-33 were withdrawn as to non-elected inventions.

In the Response filed on September 22, 2005, the Applicant amended claim 1, and cancelled claims 8 and 39.

3. Currently, claims 1, 9, 18-24, 27, 28, 34-38, and 40 are under consideration.
4. In view of the changes made to the obviousness rejection below, the action is made Non-Final.

Claim Rejections - 35 USC § 112

5. **(Prior Rejection- Withdrawn)** Claims 1, 18-24, 27, 28, and 34-40 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of reducing the infectivity of enveloped viruses, does not reasonably provide enablement for methods of reducing the infectivity of any virus. In view of the amendment to the claims, the rejection is withdrawn.
6. **(Prior Rejection- Withdrawn)** Claim 39 was rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim was rejected because the application is not enabling for embodiments of the claimed method for reducing viral

Art Unit: 1648

infectivity wherein the subject is latently infected with the target virus. In view of the cancellation of the claim, the rejection is withdrawn.

7. **(Prior Rejection- Withdrawn)** Claim 39 was rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement with respect to the genus of inventions comprising reducing the infectivity of latent viral infections through the administration of a theta defensin peptide. In view of the cancellation of the claim, the rejection is withdrawn.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. **(Prior Rejection- Maintained as restated)** Claims 1, 8, 9, 18-24, 27, 28, 34-38, and 40 were rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of Lehrer et al., WO 02/085401. These claims are directed to methods of reducing the infectivity of a virus, particularly HIV, through administration of the peptide of SEQ ID NO: 32, with or without additional anti-viral agents. The rejection is withdrawn from claims 8 as this claim has been cancelled from the application.

The Applicant traverses the rejection on the basis that the defensin of peptides 27 and 34 of Lehrer is not identical to the peptide of SEQ ID NO: 31 in the present application, and that the

Art Unit: 1648

same applies with respect to peptides 31 and 34 of Lehrer with SEQ ID NO: 32 of the present application. The Applicant asserts that no two residues align in these sequences.

It is first noted, that upon review of the rejection, the Examiner agrees with the Applicant's assertion regarding peptides 31 and 34 of Lehrer and SEQ ID NO: 32. However, the rejection is maintained based on a combination of Lehrer peptides 18 and 34.

While the Examiner notes the Applicant's linear alignments, these alignments are not considered to overcome the rejection. This is because the peptides of the present case are not linear, but circular in nature. See e.g., App., pages 5, description of Figure 4; and pages 9-10 (each section describing defensins as circular peptides). Thus, more than the linear sequence must be considered. To determine if the peptides are the same, it must be determined if the sequences share circular identity.

In present case, the claims are drawn to defensin peptides of SEQ ID NOs: 31 and 32. As indicated by the Applicant, the linear sequences of each peptide has been disclosed as follows:

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
SEQ ID NO: 31	G	I	C	R	C	L	C	R	R	G	V	C	R	C	I	C	G	R

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
SEQ ID NO: 32	G	I	C	R	C	I	C	T	R	G	F	C	R	C	I	C	G	R

The number above the letter representing each amino acid residue corresponds to the residue's position in the sequence. Because the peptides are circular in nature, they can also be represented as follows:

	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	1	2	3
SEQ ID NO: 31	R	C	L	C	R	R	G	V	C	R	C	I	C	G	R	G	I	C

Art Unit: 1648

	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	1	2	3																	
SEQ ID NO: 32	R	-	C	-	I	-	C	-	T	-	R	-	G	-	F	-	C	-	R	-	C	-	I	-	C	-	G	-	R	-	G	-	I	-	C

As the two peptides are circular in nature, this linear expression of the sequence is equally valid as that presented on page 8 of the Response.

With respect to SEQ ID NO: 31, this sequence does, as indicated in the prior action, correspond with the defensin comprising nonapeptides 27 and 34 of the Lehrer reference. The sequences of these nonapeptides are represented as follows:

27 = R - C - L - C - R - R - G - V - C 34 = R - C - I - C - G - R - G - I - C

Placing nonapeptide 27 first, the following represents an alignment of the defensin comprising peptides 27 and 34 of Lehrer with SEQ ID NO: 31 of the present application:

Lehrer 27 and 34	R	-	C	-	L	-	C	-	R	-	R	-	G	-	V	-	C	R	-	C	-	I	-	C	-	G	-	R	-	G	-	I	-	C	
	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	1	2	3																	
SEQ ID NO: 31	R	-	C	-	L	-	C	-	R	-	R	-	G	-	V	-	C	-	R	-	C	-	I	-	C	-	G	-	R	-	G	-	I	-	C

As can be seen, these sequences do align. Thus, the Applicant's argument with respect to SEQ ID NO: 31 is not found persuasive.

With respect to SEQ ID NO: 32, the Examiner agrees with the Applicant that peptides 31 and 34 of Lehrer do not correspond this sequence of the present application. However, peptides 18 and 34 do. This can be seen by a similar alignment of the defensin of Lehrer peptides 18 and 34 (respectively) with SEQ ID NO: 32, beginning with residues 4 as presented above.

Lehrer 18 and 34	R	-	C	-	L	-	C	-	T	-	R	-	G	-	F	-	C	R	-	C	-	I	-	C	-	G	-	R	-	G	-	I	-	C	
	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	1	2	3																	
SEQ ID NO: 32	R	-	C	-	I	-	C	-	T	-	R	-	G	-	F	-	C	-	R	-	C	-	I	-	C	-	G	-	R	-	G	-	I	-	C

As can be seen, these sequences also align. Thus, the Applicant's argument with respect to SEQ ID NO: 32, although found persuasive with respect to the originally cited peptides 31 and 34, is

Art Unit: 1648

not found persuasive with respect to the rejection as restated above, relying on Lehrer peptides 18 and 34.

For these reasons, and the reasons of record, the rejection is maintained.

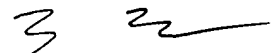
Conclusion

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Z. Lucas
Patent Examiner


JAMES HOUSEL 10/17/05
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